

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 47-51, 53, 56-66, 68-69, 74-78, 80, 82, 84-89, 91, 94-104, 106-107, 112-116, 118-121, 123-128, 130, 133-143, 145-146, 151-155, 157-159 and 164-214 are pending in the application, with 84, 123, 167, 185, and 196 being the independent claims. Claims 38, 81 and 163 have been cancelled without prejudice to or disclaimer of the subject matter therein. Claim 84 has been amended. Claims 210-214 have been added. Support for the new and amended claims can be found at paragraphs [0255]-[0262] in the specification. Claims 121 and 166 have been amended to correct typographical errors. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and further request that they be withdrawn.

***Objection to the Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 33, lines 5, 6 and 10. Office Action, page 2. Applicant has amended the specification to delete the embedded hyperlink. Accordingly, Applicants respectfully request that this objection be withdrawn.

***Claim Objections***

Claim 38 is objected to because the word "of" has been repeated twice. Office Action, page 3. Claim 163 is objected to because it depends from cancelled claims 39-46. Office Action, page 3. Applicants have cancelled claims 38 and 163 rendering the above objections moot. Accordingly, Applicants respectfully request that this objection be withdrawn.

***Sequence Compliance***

The Office Action states that this application contains sequence disclosures on several pages and within several tables that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2) and that Applicants are requested to amend the application accordingly. Office Action, page 3-4. Applicants note that all of the peptide sequences listed in Tables 1-3 and 5-6 are sequences contained within the full-length C35 polypeptide sequence of SEQ ID NO: 2 at the positions noted. As such, they do not require their own SEQ ID NOs. Paragraph 87 of the specification was amended in an Amendment and Reply filed November 22, 2002 to further clarify this.

Table 4, in addition to listing peptide sequences contained in SEQ ID NO: 2, also contains "modified" C35 peptide sequences containing amino acid substitutions. In the Amendment and Reply filed November 22, 2002, Table 4 was amended to specifically associate the sequences with the corresponding SEQ ID NOs. The modified sequences in Table 4 correspond to SEQ ID NOS: 85-147. Applicants assert that the application as

amended complies with the requirements of 37 C.F.R. §§ 1.821-1.825. Accordingly, Applicants respectfully request that this objection be reconsidered and withdrawn.

***Rejections under 35 U.S.C. § 112***

Claims 38, 81, 84, 119, 121 and 163-166 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Office Action, page 4.

Compliance with the written description requirement does not require a patent specification to describe exactly the claimed subject matter; rather, the specification must show the skilled artisan that the applicant invented what is claimed. *See Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'" (citations omitted)).

According to the Examiner, support for the phrase "wherein said polypeptide is at least 95% identical to a fragment of C35 (SEQ ID NO:2)" in claim 38 and the phrase "and additional amino acids" in claim 84 should be provided. Office Action, page 4. Applicants have cancelled claim 38. Furthermore, Applicants have amended claim 84 so that it no longer recites "and additional amino acids." Thus, the rejections with respect to these claims have been rendered moot.

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166 have been further rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Office Action, page 5. According to the Examiner, claims 38, 81, 84, 119, 121, 123, 158 and 163-166 broadly claim an isolated polypeptide comprising at least one C35 epitope defined as I-105 to V-113 of SEQ ID NO:2, as well as a fusion polypeptide that comprises an isolated C35 peptide epitope defined as I-105 to V-113 of SEQ ID NO:2 and additional amino acids.

While disagreeing with the rejection, Applicants have nevertheless cancelled claims 38, 81 and 163 in order to expedite prosecution rendering the rejection with respect to these claims moot.

With respect to claims 123, 158, and 166, Applicants note that these claims are directed to an isolated C35 peptide epitope selected from a group consisting of specifically recited C35 amino acid sequences. As such, the rationale set forth by the Examiner to support her rejection does not apply to these claims and should therefore be withdrawn.

With regard to claims 84, 119, 121 and 164-165, the Office Action further states that the fusion protein comprising the defined C35 peptide epitope and undefined amino acid sequences is not commensurate in scope with the written description. Office Action, page 6. While disagreeing with this rejection, Applicants have nevertheless amended independent claim 84 (from which claims 119, 121, 164 and 165 depend) in order to expedite prosecution. As amended, claim 84 no longer recites "and additional

amino acids." Amended claim 84 is directed to a fusion protein comprising a specifically recited C35 peptide and a polypeptide selected from a group which includes a heterologous peptide, part of the constant domain of an immunoglobulin, a heterologous signal sequence, and a marker sequence. Applicants do not need to provide the sequences of these heterologous proteins because they are known. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94; MPEP 2163, p. 2100-165, col. 2 (Rev. 1, Feb. 2003). Furthermore, the description only needs to describe what is new or not conventional. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94; MPEP 2163, p. 2100-165, col. 2 (Rev. 1, Feb. 2003).

The Examiner further states that the fusion protein potentially contains at least 107 amino acids that have not been described and the polypeptide that comprises one C35 peptide epitope is surrounded by amino acids not described in the specification. Office Action, page 6. Applicants note that neither previously presented claim 84 nor amended claim 84 requires that the fusion protein be of any particular length. Additionally, amended claim 84 is directed to a fusion protein which comprises a defined C35 epitope and a polypeptide selected from a group of recited polypeptides. As such the fusion protein has been adequately described.

Finally, according to the Examiner, the specification does not evidence the possession of all the possible variant and mutant polypeptides that could be or may not be capable of exhibiting activities of a wild type C35 polypeptide. Office Action, page 6. Applicants note that amended independent claim 84 is directed to a fusion protein which comprises a *wild-type* C35 polypeptide and a polypeptide selected from a group of specifically recited polypeptides.

As previously indicated, these fusion proteins do not need to have the same function as the wild-type C35 polypeptide, as they comprise recited CTL epitopes that are useful in diagnosis, prognostic testing, and treatment of C35-specific cancers. The specification recognizes that such proteins may have these uses in the absence of full length C35 functions, for example, at paragraphs [0064] and [0077]. In addition, the specification generally describes the use of epitopes in cancer treatment in the Background Art section, and describes the use of the C35 epitopes of the invention in cancer diagnosis, prognostic testing and treatment at numerous places in the Detailed Description and Examples. *See*, for example, pages 32-33, 179-181, 201-202, and 211-216. In Example 2 on pages 227-229, the inventors have shown that CTLs specific for a C35 epitope kill breast cancer cells.

Based on the above comments, Applicants assert that the claimed invention has been adequately described and respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

***Rejections under 35 U.S.C. § 112, first paragraph - enablement***

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166 were rejected under 35 U.S.C. 112 first paragraph, as allegedly being nonenabled for their full scope. Office Action, page 6. Applicants note that claims 38, 81 and 163 have been cancelled, rendering the rejection with respect to these claims moot.

Applicants claimed invention is directed to a polypeptide which consists of a specifically recited C35 epitope (claim 123 and dependent claims), or a fusion protein which comprises a specifically recited C35 epitope and a polypeptide selected from a

group of specifically recited polypeptides (claim 84 and dependent claims). As such, the claimed invention is directed to a finite number of C35 epitopes, and not, as the Office Action states, to a "plethora" of C35 epitopes.

Applicants assert that adequate guidance and direction is provided with respect to the claimed invention. One of ordinary skill in the art would be able to make and use the claimed invention, for example in the diagnosis or prognostic testing of C35-specific cancer as disclosed throughout the specification. Furthermore, the specification provides that C35 polypeptides and fusion proteins which comprise CTL epitopes are useful in the treatment of C35-specific cancers. In Example 2, for example, on pages 227-229, the inventors have shown that CTLs specific for a C35 epitope kill breast cancer cells. Thus the specification provides adequate guidance as to how C35 epitopes can be used. Finally, as indicated above, fusion proteins comprising C35 peptides do not need to have the same function as a wild type C35 polypeptide, as they comprise the recited CTL epitopes that are useful in diagnosis, prognostic testing, and treatment of C35-specific cancers.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

***Rejections under 35 U.S.C. § 102***

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. US2002/0052308A1. Office Action, page 6. Applicants respectfully traverse the

rejection. Claims 38, 81 and 163 have been cancelled, so the rejection with respect to these claims has been rendered moot.

With respect to the remaining claims, US2002/0052308A1 discloses a protein 131 amino acids in length (SEQ ID NO:966). Although the peptide epitope I-121 to V-129 is contained within this 131 amino acid protein, this reference does not provide any description or suggestion of the ITNSRPPCV peptide itself.

In fact, none of the peptides recited in claim 123 are disclosed in the cited publication. Thus, the cited publication does not anticipate claims 123, 158 or 166.

The Office Action also states that the disclosed C35 peptide epitope is comprised amongst 122 additional amino acids, which read on Applicants' claimed fusion protein. Office Action, page 8. Applicants note that amended claim 84 (and all pending claims depending from claim 84) are directed to a fusion protein comprising a C35 epitope and a polypeptide selected from a group of recited polypeptides which includes a heterologous epitope, a heterologous signal sequence, a heterologous functional domain, part of the constant domain of an immunoglobulin, and a marker sequence. The cited publication, thus, does not teach or suggest the fusion protein of claims 84, 119, 164 or 165. Accordingly, the cited publication does not anticipate these claims.

In the absence of a specific teaching or suggestion to make these particular epitopes, the cited publication cannot anticipate or render obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

***Rejections under 35 U.S.C. § 103***

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent Application Publication No. US2002/0052308A1. Office Action, page 9. Applicants respectfully traverse the rejection.

Applicants refer the Examiner to the arguments presented above with regard to the amended claims and rejections under 35 U.S.C. § 102. As mentioned above, the cited publication does not disclose the epitope ITNSRPPCV, or any of the other epitopes recited in the present claims. To put it simply, the 131 amino acid protein in the art and the claimed peptide ITNSRPPCV are different peptide sequences. Since the claims do not include a transitional operator such that they read on the 131 amino acid protein, the rejection cannot be maintained. In short, in the absence of a specific teaching or suggestion to make these particular epitopes, the cited publication cannot anticipate or render obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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